



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2017-0645; FRL-9986-96-OEI]

Agency Information Collection Activities; Renewal Request Submitted to OMB for Review and Approval; Comment Request; Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA): Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances (EPA ICR No. 0574.18, OMB Control No. 2070-0012). The ICR, which is available in the docket, is only briefly summarized in this document. This is a request to renew the approval of an existing ICR, currently approved through November 30, 2018. EPA previously provided a 60-day public review opportunity via the **Federal Register** on July 25, 2018. With this submission, EPA is providing an additional 30-days for public review. Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number.

DATES: Comments must be received on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number [EPA-HQ-OPP-2017-0645, to: 1) EPA online using <http://www.regulations.gov> (our preferred method)

or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460 and 2) via email to

oira_submission@omb.eop.gov. Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Adam Ross, Chemical Control Division (7404M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone: (202) 564-1625; email address: *ross.adam@epa.gov*. *For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION: Supporting documents, including the ICR that explains in detail the information collection activities and the related burden and cost estimates that are summarized in this document, are available in the docket for this ICR. The docket can be viewed online at <http://www.regulations.gov> or in person at the EPA Docket Center, West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The telephone number for the Docket Center is (202) 566-1744. For additional information about EPA's public docket, visit <http://www.epa.gov/dockets>.

Abstract: This ICR covers the information collection activities that implement the statutory mandates in section 5 of the Toxic Substances Control Act (TSCA), as amended by the Frank R.

Lautenberg Chemical Safety for the 21st Century Act of 2016, related to new chemical substances, 15 U.S.C. 2604, and the implementing regulations codified in 40 CFR parts 700, 720, 721, 723, and 725. Specifically, TSCA section 5 requires that any person who proposes to manufacture (which includes import) a new chemical substance (i.e., a chemical substance not listed on the TSCA section 8(b) Inventory) or a significant new use of a chemical substance (as identified by EPA rule) must provide a notice to EPA at least 90 days prior to commencing the manufacture of that chemical substance. EPA must review the section 5 notice, make an affirmative determination on the safety of the new chemical substance or significant new use, and, if appropriate, regulate the chemical substance to address any unreasonable risks identified before it can proceed to the marketplace. TSCA section 5 authorizes EPA to determine by rule that a use of a chemical substance is a significant new use requiring notice to and review and determination by the Agency through a significant new use rule (SNUR) that requires any person who proposes to manufacture or process a chemical substance for a designated new use to submit a Significant New Use Notice (SNUN) to the Agency. EPA must review the SNUN, make a determination on the chemical substance, and take appropriate action pursuant to TSCA section 5. The submitter of a premanufacture notice (PMN), significant new use notice (SNUN), or microbial commercial activity notice (MCAN) is also required to inform EPA when non-exempt commercial manufacture of the substance in question actually begins by submitting a Notice of Commencement (NOC). Under TSCA section 5, EPA must make one of five possible regulatory determinations with respect to the new chemical substance or significant new use and take action, as appropriate, to ensure adequate protection of human health and the environment. If EPA takes no action within the 90-day review period for PMNs (or 30 or 45 days for PMN exemption applications), TSCA section 5 states that the PMN submitter is entitled to receive a

refund of fees paid. Respondents may claim all or part of a response confidential. EPA will disclose information that is covered by a claim of confidentiality only to the extent permitted by, and in accordance with, the procedures in TSCA section 14 and 40 CFR part 2.

Form Numbers: Premanufacture Notice (EPA Form No. 7710-25) and Notice of Commencement of Manufacture or Import (EPA Form No. 7710-56).

Respondents/affected entities: Companies that manufacture, process or import chemical substances.

Respondent's obligation to respond: Mandatory.

Frequency of response: On occasion.

Estimated total number of respondents: 234.

Estimated total burden: 135,230 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Estimated total cost: \$49,979,150 (per year), includes \$0 annualized capital or operation and maintenance costs.

Changes in the Estimates: There is an increase of 18,054 hours in the total estimated respondent burden compared with that currently approved by OMB. This increase reflects an adjustment in EPA's estimated number of each type of notice; the estimated number of annual CDX registrants; and EPA corrected some discrepancies in estimating burden from the previous ICR. This increase also reflects a program change from incorporating burden associated with new CBI substantiation requirements resulting from the 2016 amendment to TSCA and the inclusion of burden associated with the "*Points to Consider When Preparing TSCA New Chemical Notifications*" guidance document.

Dated: November 19, 2018.

Courtney Kerwin,

Director, Collection Strategies Division.

[FR Doc. 2018-25778 Filed: 11/26/2018 8:45 am; Publication Date: 11/27/2018]